K000456

JUN - 1 2000

510(k) Summary for the Harvest Dual Liquid Applicator

Submitter's Name and Address:	Harvest Technologies Corp. 77 Accord Park Drive, D-7
Phone Number:	781-982-1900
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Contact Person:	Annette M. Fagnant, Director, Regulatory Affairs
Date Summary Prepared:	February 1, 2000
Device Trade Name:	Harvest Dual Liquid Applicator
Common Name:	Dual Liquid Applicator
Classification Name:	Syringe, Irrigating (880.6960)
Substantial Equivalence:	The Harvest Dual Liquid Applicator is substantially equivalent to other dual liquid dispensers previously cleared by the FDA via the 510(k) process (e.g., Micromedics Surgical Sealant Dispenser)
Device Description:	Harvest Applicator will be configured using the following components: • Two commercially available disposable medical piston syringes, • Applicator tip (straight tip or spray) manufactured by Micromedics Inc., • Handle frame, and • Plunger clip.
Intended Use:	Indicated for simultaneous delivery of two non-homogenous liquids to the same area.
Technological Characteristics:	The proposed device has the same technological characteristics and is similar in design and configurations compared with the predicate device (see Table 5-1, next page).

Table 5-1 Summary Comparison Harvest Applicator and Micromedics SSD		
	Applicator	
Characteristic	**Harvest Applicator (This submission)**	**Micromedics SSD (K881020 and K883338)**
Intended Use	Indicated for simultaneous delivery of two non-homogeneous liquids to the same area.	Same
Components	• ABS applicator tip in straight and spray configurations • Includes commercially marketed syringes, fits syringes up to 20cc in size • Plunger Clip • Applicator frame/handle	Same
Handle Configuration	Pistol-grip (clips to one syringe barrel)	Frame (two syringe barrels clipped into frame)
Principle of Operation	Fluids simultaneously dispensed from the applicator tip by depressing the plunger clip that attaches the plungers from the two syringes.	Same
Sterilization	Gamma irradiation (Handle and Plunger Clip) Ethylene Oxide (Applicator Tips)	Ethylene Oxide

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2000

Ms. Annette M. Fagnant
Director, Regulatory Affairs
Harvest Technologies Corporation
77 Accord Park Drive, D-7
Norwell, Massachusetts 02061

Re: K000456
Trade Name: Harvest Technologies Dial Liquid Applicator
Regulatory Class: II
Product Code: FMF
Dated: April 17, 2000
Received: April 19, 2000

Dear Ms. Fagnant:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control,
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K000456

Device Name: Harvest Technologies Dual Liquid Applicator

Indications for Use: The Harvest Technologies Dual Liquid Applicator is designed to allow for the simultaneous delivery of two non-homogeneous liquids to the same site.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rebecca Cucente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000456

Prescription Use ✓ **OR** **Over-The-Counter Use**____
(Per 21 CFR 801.109)

v (Revised)